Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD 20850

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In the Matter of

Laser Products; Proposed Amendment to	)	
Laser Performance Standard;	)	Docket No. 93N-0044
21 CFR Parts 1010 and 1040	)	

COMMENTS OF THE CONSUMER ELECTRONICS MANUFACTURERS ASSOCIATION

The Consumer Electronics Manufacturers Association (CEMA), a sector of the Electronic Industries Alliance (EIA), is the principal U.S. trade association of the consumer electronics industry. The 500 CEMA members, ranging from large corporations to small businesses, have facilities throughout the United States. CEMA members design, manufacture, export, distribute and sell a wide variety of consumer electronics products, including audio, video, accessories, mobile electronics, communication, information and multimedia products that are sold through consumer channels. CEMA also sponsors and manages the International Consumer Electronics Show (CES), the world's largest annual trade event showcasing consumer electronics products.

CEMA RESPONSE TO ISSUES FOR PUBLIC COMMENT

I. CEMA Support of Harmonization Efforts

CEMA generally supports the Food and Drug Administration's (FDA's) proposal to amend the performance standard for laser products as announced in the *Federal Register* on March 24, 1999.

In May 1996, in a letter to FDA's Center for Devices and Radiological Health, CEMA urged the agency to consider measures to harmonize U.S. requirements and recognized international standards while maintaining the high margins of radiation safety currently demonstrated by consumer electronics products. In its letter, CEMA suggested that harmonization would streamline current administrative procedures for FDA as well as the consumer electronics industry. CEMA argued that harmonization would reduce costs faced by consumer electronics manufacturers who currently must produce variations of products in order to meet differing regulatory requirements in the U.S. and abroad. In addition, by harmonizing regulations and

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streamlining procedures, CEMA suggested that FDA's regulatory resources could be focused more efficiently and effectively on areas of particular concern to the agency, such as non-compliance.

II. Adoption of IEC Certification Label

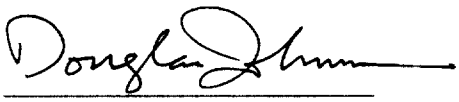
In its letter to FDA in March 1996, CEMA proposed that FDA adopt the IEC certification label for Class 1 laser products. Enclosed with the letter was an example of the IEC laser label graphic. CEMA supports FDA's adoption of the IEC certification label for Class 1 laser products.

III. Comments on Table 7

In Table 7 of 21 CFR Part 1040 ("Accessible Emission Limits for Collateral Radiation from Laser or LED Products"), references to LEDs should be eliminated.

Respectfully submitted,

CONSUMER ELECTRONICS
MANUFACTURERS ASSOCIATION

By: 

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June 22, 1999

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